

### **REMARKS**

This Amendment is responsive to the Final Office Action dated April 30, 2009. Applicant has amended claims 17 and 36, and has cancelled claim 18 without prejudice. (Applicant previously cancelled claims 1–16, 20–35, 38, and 41.) Applicant has also added new claims 50–53, which are fully supported by the original disclosure. Claims 17, 19, 36, 37, 39–40, 42–53 are pending upon entry of this Amendment.

### **Interview Summary Record**

As per the requirements of MPEP §713.04, the present summary constitutes a summary record of the substance of the interview between Applicant's representative, Raymond R. Berdie (Reg. No. 50,769) and the Examiner on July 20, 2009. Applicant's representative wishes to thank the Examiner for agreeing to this telephonic interview.

During the interview, Applicant's representative and the Examiner discussed the following item with respect to the Final Office Action dated April 30, 2009: the rejection of claims 17–19, 36–37, and 39–49 under either 35 U.S.C. 102(b) as being anticipated by Kinoshita et al. (US 6,280,434), or under 35 U.S.C. 103(a) as being obvious in view of Kinoshita et al. No exhibits were shown. Applicant's representative argued that Kinoshita did not appear to disclose or suggest feature of the claims. The Examiner provided additional clarification regarding his interpretation of Figure 3 of Kinoshita with respect to Applicant's claims. No formal agreement was reached.

### **Claim Rejection Under 35 U.S.C. § 102 and 35 U.S.C. § 103**

In the Final Office Action, the Examiner rejected claims 17–19, 36–37, and 39–49 under either 35 U.S.C. 102(b) as being anticipated by Kinoshita et al. (US 6,280,434, hereinafter "Kinoshita"), or under 35 U.S.C. 103(a) as being obvious in view of Kinoshita. Applicant respectfully traverses this rejection to the extent that it may be considered applicable to the amended claims. Kinoshita fails to disclose, or even suggest, every feature of the amended claims, and provides no teaching that would have suggested the desirability or rational reason of modification to include such features.

Applicant has amended the pending claims to require a catheter/catheter assembly having one or more openings formed on a sidewall, where at least one of the openings is formed on the

sidewall at an acute angle with respect to a longitudinal axis of a portion/end of the catheter/catheter assembly that contains the sidewall, such that forces resulting from fluid flow out of the openings on the sidewall and from fluid flow out of the elastic restrictor are substantially balanced in both axial and radial directions with respect to the specified longitudinal axis. Kinoshita fails to disclose or suggest all of these features.

In support of the rejection, the Examiner primarily made reference to Figure 3, the Abstract, and column 2 of Kinoshita. Neither these nor any other sections of Kinoshita, however, disclose or suggest the features recited above. Furthermore, Kinoshita also fails to disclose or suggest an elastic restrictor, on the distal end of the catheter/catheter assembly, where the elastic restrictor changes size in response to a change in fluid flow through the catheter/catheter assembly to provide a variable amount of fluid force restriction as fluid flows through the elastic restrictor, as is also required by Applicant's pending claims.

The Abstract of Kinoshita states that an angiographic catheter has a plurality of minute side apertures formed in a portion that is located toward a proximal end of the catheter from the deformed portion. Though these minute side apertures of Kinoshita may be formed in a portion of the catheter that is located towards a proximal end of the catheter, the apertures themselves are not formed on the sidewall at an acute angle with respect to a longitudinal axis of a portion/end of the catheter that contains the sidewall.

The Abstract of Kinoshita, in addition to the disclosure in column 2, states that the side apertures 4 are arranged such that a reaction force generated by injection of a contrast medium 8 from the distal end opening 3 is counterbalanced by the contrast medium injected from the side apertures 4. However, Kinoshita states the following in lines 23–36 of column 4:

If the side apertures 4 have too large a diameter, the contrast medium 8 tends to be injected from the side apertures 4 not perpendicularly to an axis of the catheter but obliquely toward the distal end thereof. Hence, the reaction force generated by injection of the contrast medium 8 from the side apertures 4 may move the distal end portion of the catheter 1 toward the proximal end portion thereof. On the contrary, if the side apertures 4 have too small a diameter, there arises a great resistance against injection of the contrast medium 8 from the side apertures 4.

Kinoshita also states, in lines 28–32 of column 5, that “the jet stream of the contrast medium 8 injected from the distal end opening 3 flows substantially perpendicularly to the axis of the portion of the catheter 1 where the side apertures 4 are formed.” Thus, in order for the catheter

of Kinoshita to work properly in counterbalancing the fluid forces as contrast media exits opening 3 and side apertures 4, contrast media must be injected from side apertures 4 **perpendicularly** to an axis of the catheter where side apertures 4 are formed (as shown in FIG. 3 of Kinoshita), and **not** obliquely toward an end of the catheter. Thus, Kinoshita cannot possibly disclose or suggest a catheter/catheter assembly having one or more openings formed on a sidewall, where at least one of the openings is formed on the sidewall at an acute angle with respect to a longitudinal axis of a portion/end of the catheter/catheter assembly that contains the sidewall, as required by Applicant's pending claims. In fact, nowhere does Kinoshita even suggest that side apertures 4 may be formed on the sidewall of the catheter described in Kinoshita at any form of acute angle with respect to the axis of the catheter where side apertures 4 are formed.

FIG. 3 of Kinoshita shows that the jet stream of the contrast medium 8 injected from opening 3 flows substantially perpendicularly to the axis of the portion of the catheter where side apertures 4 are formed. FIG. 3 shows that some of the contrast medium 8 injected from opening 3 does not flow completely perpendicular to the axis of the portion of the catheter where side apertures 4 are formed. However, the fluid force components from this fluid flow out of opening 3 (i.e., the fluid force components in the upward and downward directions with respect to the axis of the portion of the catheter where side apertures 4 are formed) are directly counter-balanced irrespective of the fluid flowing out of side apertures 4.

As a result, only the fluid flow out of opening 3 that does, in fact, flow substantially perpendicularly to the axis of the portion of the catheter where side apertures 4 are formed is counterbalanced by the fluid flowing in the opposite direction out of side apertures 4 perpendicularly to the axis of the catheter. As a result, there would have been absolutely no need or rational reason for one of skill in the art, at the time of Applicant's invention, to modify side apertures 4 of Kinoshita such that they would be formed along the sidewall at an acute angle with respect to the axis of the catheter where side apertures 4 are formed, as required by Applicant's claims. In Kinoshita, contrast media **must** be injected from side apertures 4 **perpendicularly** to an axis of the catheter where side apertures 4 are formed in order to counter-balance the fluid forces of fluid flowing in the opposite direction out of opening 3.

Kinoshita does contemplate that various different forms of side apertures 4 may be used. For example, in lines 11–15 of column 4, Kinoshita states that side apertures 4 are formed in the

flank of catheter 1 at which the deformed portion 2 is directed, preferably over a central angle from 100 degrees to 200 degrees. However, the range of values of the central angle relates only to a **forming area** of side apertures 4 on the catheter itself. Thus, in Kinoshita, side apertures 4 may be formed on various sections around the periphery of the catheter, depending on the central angle (or central angle range) of the forming area. However, the central angle has nothing to do with the angles at which side apertures 4 are formed on the catheter sidewall, or the angle at which contrast media flows out of side apertures 4. (Lines 36–39 of column 5 also states that a small number of side apertures 4 may be formed in a flank portion of catheter 1 that is opposite to the portion at which deformed portion 2 is directed. Again, this relates only to the placement of the side apertures 4 on the periphery of the catheter itself, and not with the angle at which side apertures 4 are formed on the catheter sidewall or the angle at which fluid exits such side apertures 4.)

Lines 43–61 of column 4 of Kinoshita provide additional details on alternate configurations of side apertures 4. For example, Kinoshita describes that each side aperture 4 may be shaped as an elongated ellipse or an oval, and provides certain dimensions for the major and minor axes of the formed side apertures 4. Kinoshita further describes that the side apertures 4 are provided so that the major axis may be substantially parallel or diagonal with the axial direction of the catheter.

Again, these portions of Kinoshita relate to the placement or shape of the side apertures 4 on the periphery of the catheter itself, and not with the angle at which side apertures 4 are formed on the catheter sidewall or the angle at which fluid exits such side apertures 4.) Thus, Kinoshita fails to disclose or suggest a catheter/catheter assembly having one or more openings formed on a sidewall, where at least one of the openings is formed on the sidewall at an acute angle with respect to a longitudinal axis of a portion/end of the catheter/catheter assembly that contains the sidewall, as required by Applicant's pending claims.

Furthermore, Applicant further submits that Kinoshita fails to disclose or suggest, on a distal end of a catheter/catheter assembly, an elastic restrictor that, when operable, changes in size in response to a change in fluid flow to provide a variable amount of fluid force restriction as fluid flows through said elastic restrictor. In the Office Action, the Examiner interpreted the opening 3 of Kinoshita as an elastic restrictor. Applicant disagrees with this interpretation. Nowhere does Kinoshita indicate that opening 3 comprises an **elastic** restrictor. Additionally,

Kinoshita fails to disclose or suggest that opening 3 has the capability of **changing in size** in response to a change in fluid flow within the catheter, thereby providing a **variable** amount of fluid force restriction as fluid flows through opening 3. As a result, Applicant submits that Kinoshita further fails to disclose or suggest, on a distal end of a catheter/catheter assembly, an elastic restrictor that, when operable, changes in size in response to a change in fluid flow to provide a variable amount of fluid force restriction as fluid flows through said elastic restrictor, as required by Applicant's claims.

For at least these reasons, the Examiner has failed to establish a prima facie case for the non-patentability of Applicant's pending claims under either 35 U.S.C. 102(b) or 35 U.S.C. 103(a). Withdrawal of these rejections is therefore respectfully requested.

### **New Claims**

Applicant has added new claims 50–53 to the present application. These new claims are fully supported by the original disclosure. New claims 50–53 are each dependent upon one of independent claims 17 or 36 as presently amended. For at least the reasons outlined above regarding amended claims 17 and 36, Applicant further submits that Kinoshita also fails to disclose or suggest every feature of new claims 50–53.

Furthermore, Applicant submits that Kinoshita fails to disclose or suggest the additional features recited by new claims 50–53. For example, Kinoshita fails to disclose or suggest any form of elastic restrictor that is formed along the longitudinal axis of a portion of the catheter/catheter assembly containing the sidewall on which the opening(s) is/are formed. The opening 3 of Kinoshita is not an elastic restrictor, as outlined above. Furthermore, opening 3 is not formed along the longitudinal axis of the portion of the catheter containing side apertures 4.

In addition, Kinoshita fails to disclose or suggest that, with respect to the longitudinal axis of a portion of the catheter/catheter assembly containing the sidewall on which the opening(s) is/are formed, at least one axial force vector component resulting from fluid flow out of said at least one angled opening is substantially balanced by an axial force vector component resulting from fluid flow out of said elastic restrictor. Nowhere does Kinoshita even suggest balancing these types of fluid flow forces. In Kinoshita, with respect to the axis of the portion of the catheter on which side apertures 4 are formed, there are **no** axial force vector components

resulting from fluid flow out of side apertures 4, because side apertures 4 are not formed on the sidewall at an acute angle with respect to the axis of this sidewall (or portion of the catheter).

Therefore, for at least these reasons, Applicant respectfully requests consideration and allowance of new claims 50-53.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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